AdvocateAuroraHealth[™]

REGEN-COV EUA Update August 6, 2021

TYPE OF INFORMATION: Clinical Practice Change INTENDED AUDIENCE: Physicians, Nurses, Pharmacists

Situation	The FDA recently updated the emergency use authorization (EUA) for the COVID monoclonal (27.07), 0.01)
S	antibody combination casirivimab + imdevimab (REGEN-COV).
Background	• The EUA for REGEN-COV was expanded to allow use for post-exposure prophylaxis against
В	COVID-19 in individuals who are at least 12 years of age, weigh at least 40 kg, are at high rist for progression to severe COVID-19 disease, and are:
	 not fully vaccinated or who are not expected to mount an adequate immune respons to complete SARS-CoV-2 vaccination (for example, individuals with
	immunocompromising conditions including those taking immunosuppressive medications) and
	 have been exposed to an individual infected with SARS-CoV-2 consisten with close contact criteria per CDC or
	 who are at high risk of exposure to an individual infected with SARS-CoV 2 because of occurrence of SARS-CoV-2 infection in other individuals in the same institutional setting (for example, nursing homes, prisons)
	 Criteria for designating a patient as high risk for progression to severe COVID-19 are the same as those used for treatment of COVID-19 with REGEN-COV.
Assessment	The dose and administration for prophylaxis is the same dose currently used for treatment
Α	of COVID-19: casirivimab/imdevimab 600mg/600mg over 20 minutes.
	- Patients must be observed for at least 60 minutes post-infusion for any
	symptoms of hypersensitivity reaction.
	 Epic orders for REGEN-COV will now ask prescribers to indicate whether REGEN-COV is being used for treatment or prophylaxis and then attest that the patient meets criteria.
	 The patient/family/caregiver fact sheet must be provided prior to the infusion. The link has been updated in Epic.
	 The same sites (ED and infusion clinics on a hospital campus) that are currently
	administering REGEN-COV for treatment may now also give REGEN-COV for prophylaxis if
	they have the capacity to do so. No additional sites will be added at this time.
	 The EUA also authorizes the use of REGEN-COV given as four subcutaneous injections. AAH will not be offering that option for either treatment or prophylaxis at this time. IV infusion
	the preferred method per the EUA.
Recommendation	Effective immediately, AAH will offer REGEN-COV IV infusions for the indication of post-
R	exposure prophylaxis against COVID-19 as defined above.
N	 The dose for prophylaxis is casirivimab/imdevimab 600mg/600mg.
	• Epic orders have been updated to add prophylaxis as an indication for prescribers.
	Questions? Please contact: Drug Policy Center at DPC@aah.org

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